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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,299	10/25/2001	Stewart Thomas Leslie	208.1009	4506

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EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1615	9

DATE MAILED: 03/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/037,299	Applicant(s) LESLIE, STEWART THOMAS	
	Examiner Micah-Paul Young	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Acknowledgment of Papers Received: Amendment dated 01/02/03.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1 – 17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Miranda et al (USPN 5474783). The claims are drawn to composition and transdermal delivery device containing said composition. The composition comprises an opioid analgesic and another agent. The other agent is recited to be non-permeant, and an emetic, nauseant, or bitter tasting substance. The composition further comprises a vehicle, which will include both agents and a penetration enhancer. Claims 10 – 13 and 15 are drawn to a transdermal device containing the opioid composition. The device can either be a monolithic device or a reservoir system. The device is recited to contain buprenorphine, atropine and a penetration enhancer.

Miranda et al discloses a transdermal device containing a composition comprising as possible active agents, buprenorphine and atropine. The device of the reference can either be monolithic or comprise a reservoir system, but will in both instances comprise a backing layer that is respectively impermeable. The formulation further comprises penetration enhancers, and

other excipients common in the art (Abstract; col. 4, lin. 3 – 5, 29 – 44; col. 11, lin. 1 – 8; col. 11, lin. 37 – 41; col. 12, lin. 55 – 60; col. 14, lin. 17 – 20; examples; claims).

Though the reference teaches the general composition of atropine and buprenorphine and a penetration enhancer it does not teach the intended use of applicant. Applicant claims that the atropine (or an analogous substance) is used as a distressing agent that causes distress to the user. These recitations are an intended use for the composition and are not given patentable weight in determinations of patentable distinction. Applicant claims a composition of matter, comprising an opioid, a separate non-permeant agent, and a penetration enhancer. The examiner has presented by way of prior art a composition and device that is obvious over the claimed invention. Also, Miranda does not explicitly claim the use of atropine and buprenorphine in combination, the reference only suggests their presence as possible active agents, as well as suggesting the presence of multiple drugs at once. One of ordinary skill in the art would have been motivated to follow the suggestions of Miranda to combine the possible agents (atropine and buprenorphine) in order to fight a wider range of ailments. A skilled artisan also would have been motivated to follow the suggestion in the art to include a penetration enhancer in order to better transmit the active agents across and into the skin. It would have been obvious to one of ordinary skill in the art, at the time of the invention to follow the suggestions of Miranda with an expected result of a composition comprising atropine, buprenorphine, a penetration enhancer and a device to transmit it into the skin.

Response to Arguments

3. Applicant's arguments filed 01/02/03 have been fully considered but they are not persuasive. Applicant argues:

a. Miranda does not teach a transdermal where one agent is NOT permeated through the skin.

With regard to this argument a., applicant is reminded that the claims are drawn to the composition comprising particular agents. Applicant recites the use of atropine and opioid analgesic in a transdermal formulation. Miranda presents this composition. Applicant's recitation of a distressing agent not permeating the skin, are deemed a future intended use, or mechanism and do not distinguish the present invention form the prior art. Applicant is reminded that where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997)

Furthermore the compositions claimed by applicant and those presented by the examiner appear to be the same and/or similar, burden has been shifted to applicant to come forth with evidence of a non-obvious difference between the two. See *In re Marosi,* 710 F.2d. 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

As discussed in the rejection, a skilled artisan would have been motivated to use/modify the product of Miranda in order to achieve the delivery of an opioid analgesic. Given the composition of the transdermal, it would have been obvious to that skilled artisan at the time of the invention.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Quan et al (USPN 5601839) teaches a transdermal formulation and device comprising a penetration enhancer, an opioid and atropine. Andriola et al (USPN 4666441)

teaches a transdermal formulation and device comprising a narcotic and atropine. Fallen et al (USPN 5352456) teaches a monolithic transdermal device and formulation comprising atropine, buprenorphine and a permeation enhancer. Zaffaroni (USPN 3797494) and Gale et al (USPN 5635203) both teach transdermal formulations comprising narcotic substances and atropine.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young
March 27, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600